IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al. v. AMERICAN HOME PRODUCTS CORPORATION	)	CIVIL ACTION NO. 99-20593
	)	2:16 MD 1203

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J. August 30, 2007

Joyce Wright ("Ms. Wright" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In June 2002, claimant submitted a Green Form to the Trust signed by her attesting physician, Roger W. Evans, M.D. Based on an echocardiogram dated May 19, 2000, Dr. Evans attested in Part II of claimant's Green Form that she suffered from: (1) moderate mitral regurgitation; (2) an ejection fraction in the range of 50% to 60%; (3) pulmonary hypertension secondary to moderate or greater mitral regurgitation; and (4) an abnormal left atrial dimension. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $545,310.[3]

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not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Under the Settlement Agreement, a claimant is entitled to
(continued...)

In the report of claimant's echocardiogram, James E. Sear, M.D., the reviewing cardiologist, stated that "[d]oppler flow analysis reveals moderate mitral regurgitation ...." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Sear also estimated claimant's ejection fraction as 55%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b).

Dr. Sear further determined that there was evidence that claimant had "modest" pulmonary hypertension. Under the Settlement Agreement, pulmonary hypertension secondary to valvular heart disease is present when the peak systolic pulmonary artery pressure is greater than 40 mm Hg measured by cardiac catheterization or greater than 45 mm Hg measured by Doppler Echocardiography, at rest. See id. § IV.B.2.c.(2)(b). Finally, it appears that Dr. Sear measured claimant's left atrial

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Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Here, the Trust has contested claimant's level of mitral regurgitation and three complicating factors, each of which is one of the conditions needed to qualify for a Level II claim. In order to receive Matrix Benefits, claimant must establish that there is a reasonable medical basis for finding that she has moderate mitral regurgitation and at least one of the three complicating factors at issue.

dimension as 4.5 cm. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view.[4] See id. § IV.B.2.c.(2)(b).

In August 2003, the Trust forwarded the claim for review by Michael E. Staab, M.D., one of its auditing cardiologists. In audit, Dr. Staab reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for any of Dr. Evans' representations. More specifically, Dr. Staab found that claimant had only mild mitral regurgitation and her echocardiogram tape showed "[o]nly an early systolic MR jet" with "a lot of speckled blue that is not contiguous with actual jet." Dr. Staab also concluded that claimant's ejection fraction was greater than 60%. Finally, Dr. Staab stated that he could not evaluate claimant's left atrial dimension or pulmonary artery pressure due to the poor technical quality of the echocardiogram tape. Dr. Staab stated that "[t]his was an impressively bad study. I recognize that the patient was very obese, but the sonographer could have done a much better job with [the] gain/TGC controls."

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4. Dr. Evans also prepared a report on claimant's May 19, 2000 echocardiogram. Therein, Dr. Evans determined that claimant's RJA/LAA ratio was 25%, her ejection fraction was 55%, her pulmonary artery pressure was 50 mm Hg and her left atrium measured 4.5 cm.

Based on Dr. Staab's diagnoses, the Trust issued a post-audit determination denying Ms. Wright's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[5] In contest, claimant submitted a verified statement by her attesting physician, Dr. Evans. Therein, Dr. Evans reiterated his Green Form representations and stated that: (1) claimant's mitral regurgitation was best seen in the apical four-chamber views where the "jet extends all the way to the back of the left atrium" and "[i]ts width is approximately one-third of the width of the left atrium"; (2) the correct ejection fraction measurement was 55%; and (3) the left atrium dimension was evaluable and showed an abnormal left atrial antero-posterior systolic dimension of 4.5 cm in the parasternal long-axis view.[6]

Claimant also submitted verified statements by G. Whitney Reader, M.D., and Gregory R. Boxberger, M.D. Dr. Reader concluded that claimant's RJA/LAA ratio was greater than 25%, her left atrial dimension was "exactly 4.0 cm" and her ejection

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for the Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Wright's claim.

6. Dr. Evans also explained that he could not actually measure the pulmonary artery pressure, but that "on the basis of the remainder of the accurate findings from the original echo tape interpretation, and their finding of a right ventricular systolic pressure of 45 mmHg, I believe that this is a reasonable and accurate finding."

fraction was "mildly reduced to 50-60%." Dr. Boxberger concluded that claimant's RJA/LAA ratio was approximately 25%, her ejection fraction was 60% and she had an abnormal left atrial antero-posterior systolic dimension of 4.2 cm in the parasternal long-axis view.[7] Claimant argued that the auditing cardiologist did not understand the difference between his personal opinion and the reasonable medical basis standard and that the findings of Drs. Evans, Reader and Boxberger provide a reasonable medical basis for her claim.

The Trust then issued a final post-audit determination, again denying Ms. Wright's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807 (Mar. 26, 2003), Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Wright's claim should be paid. On September 7, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3901 (Sept. 7, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special

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7. Dr. Boxberger also concluded that there was a reasonable medical basis for the attesting physician's finding of pulmonary hypertension. Dr. Reader, however, found that he could not evaluate claimant's pulmonary hypertension because "no Doppler information [was] taken to evaluate pulmonary hypertension ...."

Master. The Trust submitted a reply on November 4, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[8] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. Rule 35.

The issues presented for resolution of this claim are whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings of moderate mitral regurgitation and either a reduced ejection fraction, pulmonary hypertension secondary to moderate mitral regurgitation, or an abnormal left atrial dimension. See id. Rule 24. Ultimately, if we determine that there was no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id.

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8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Rule 38(a). If, on the other hand, we determine that there was a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Wright reiterates that the opinions of Dr. Evans as well as Drs. Reader and Boxberger demonstrate that there is a reasonable medical basis for her claim. Finally, claimant contends that inter-reader variability accounts for the differences in opinion between the auditing cardiologist and her physicians.

In response, the Trust argues that claimant misinterprets the concept of inter-reader variability.[9] The Trust also contends that the standard of review is whether there is a reasonable medical basis for the attesting physician's findings and not whether one party can collect more opinions than the other. Finally, the Trust asserts that Dr. Reader found claimant's left atrial dimension to be normal, which undermines the attesting physician's finding of an abnormal left atrial dimension.[10]

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9. In its show cause submissions, the Trust also argues that, under Rule 26(a)(2) of the Federal Rules of Civil Procedure, physicians who proffer opinions regarding claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. We disagree. We previously stated that Rule 26(a)(2) disclosures are not required under the Audit Rules. See PTO No. 6996 (Feb. 26, 2007).

10. In a sur-reply, claimant reiterated her arguments concerning the reasonable medical basis standard and inter-reader variability.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there is a reasonable medical basis for Dr. Evans' findings of moderate mitral regurgitation and a reduced ejection fraction. As explained by Dr. Vigilante:

> Mitral regurgitation was noted in all views including the parasternal long axis view, parasternal short axis view, apical four chamber view, and apical two chamber view. There was a central to slightly lateral jet of mitral regurgitation present. The RJA and LAA were measured in several cardiac cycles. I determined the RJA/LAA ratio to be 28%. The left ventricle was slightly dilated but had normal wall motion throughout. However, the left ventricle was not hyperdynamic in contractility. The left ventricular ejection fraction was measured at 60% via Simpson's Rule.[11]

In response to the Technical Advisor's Report, claimant argues that Dr. Vigilante's conclusions support her attesting physician's findings of moderate mitral regurgitation and a reduced ejection fraction. As a result, claimant contends that she is entitled to Matrix Benefits.[12]

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for her

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11. Dr. Vigilante concluded that there was no reasonable medical basis for finding an abnormal left atrial dimension. Dr. Vigilante also stated that "I was able to measure the TR jet via continuous wave Doppler and noted a peak velocity of 3.1 meters per second. This translated into a peak systolic pulmonary artery pressure estimated at 48 mmHg assuming a right atrial pressure of 10 mmHg."

12. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

claim. Claimant's attesting physician, Dr. Evans, reviewed claimant's echocardiogram and found, among other things, that claimant had moderate mitral regurgitation and a reduced ejection fraction.[13] Although the Trust contested the attesting physician's conclusions, Dr. Vigilante confirmed these findings. Specifically, Dr. Vigilante concluded that claimant had moderate mitral regurgitation with an RJA/LAA ratio of 28% and that she had an ejection fraction of 60%.

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA, and an ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See Settlement Agreement §§ I.22, IV.B.2.c.(2)(b). Here, Dr. Vigilante measured claimant's RJA and LAA in several cardiac cycles and determined her "RJA/LAA ratio to be 28%." Dr. Vigilante also measured claimant's ejection fraction as 60%. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.[14]

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13. Although unnecessary for resolution of this claim, as noted above, claimant also submitted expert reports of two additional cardiologists who similarly concluded that claimant had moderate mitral regurgitation and a reduced ejection fraction.

14. Accordingly, we need not address claimant's remaining arguments. We also need not address whether claimant had an abnormal left atrial dimension or pulmonary hypertension secondary to moderate mitral regurgitation.

For the foregoing reasons, we conclude that claimant has met her burden of proving that there is a reasonable medical basis for her claim and is consequently entitled to Matrix A-1, Level II benefits. Therefore, we will reverse the Trust's denial of the claim submitted by Ms. Wright for Matrix Benefits.

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PRETRIAL ORDER NO.

AND NOW, on this 30th day of August, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is REVERSED and that claimant Joyce Wright is entitled to Matrix A-1, Level II benefits. The Trust shall pay such benefits in accordance with the Settlement Agreement and Pretrial Order No. 2805, and shall reimburse claimant for any Technical Advisor costs incurred in the Show Cause process.

BY THE COURT:

/s/ Harvey Bartle III
C.J.